



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/802,061

03/15/2004

Gordon W. Duff

24299-508-CON3

4104

30623

7590

06/14/2006

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,061	DUFF ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 1-22 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed kits comprise distinct nucleic acids. A reference against one nucleic acid molecule would not be a reference against each of the other nucleic acid molecules. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1, 3, 5 and 6, drawn to kits comprising a nucleic acid that hybridizes to an allele of 1731 IL-RN or a means for detecting an allele of 1731 IL-RN, classified in class 536, subclass 23.1.
2. Claims 1, 3, 5 and 7, drawn to kits comprising a nucleic acid that hybridizes to an allele of 1812 IL-RN or a means for detecting an allele of 1812 IL-RN, classified in class 536, subclass 23.1.
3. Claims 1, 3, 5 and 8, drawn to kits comprising a nucleic acid that hybridizes to an allele of 1868 IL-RN or a means for detecting an allele of 1868 IL-RN, classified in class 536, subclass 23.1.

Art Unit: 1634

4. Claims 1, 3, 5 and 9, drawn to kits comprising a nucleic acid that hybridizes to an allele of 1887 IL-RN or a means for detecting an allele of 1887 IL-RN, classified in class 536, subclass 23.1.
- 5 – 18. Claims 1, 3, 5, and one of claims 10-22, drawn to kits comprising a nucleic acid that hybridizes to one of the alleles as recited in claims 1 and 5 and 10-22, classified in class 536, subclass 23.1. Each group is considered a separate and distinct invention. For example, group 5 represents kits comprising a nucleic acid that hybridizes to an allele of 8006 IL-RN and includes claims 1, 3, 5 and 10; group 6 represents kits comprising a nucleic acid that hybridizes to an allele of 80061 IL-RN and includes claims 1, 3, 5 and 11, etc. Upon election of one of these groups, Applicants should clarify the allele corresponding to the elected group.
- 19 - 153. Claims 1-4, drawn to kits comprising a combination of 2 or more nucleic acids, classified in Class 536, subclass 23.1 . Each of groups 9-153 is considered a separate and distinct invention. For example, group 9 represents kits comprising a nucleic acid that hybridizes to an allele 4 of the 222/223 marker of IL-1A and allele 4 of the gz5/gz6 marker of IL-1A and particularly includes claims 1-4. Upon election of one of these groups, Applicants should clarify the alleles corresponding to the elected group. For instance, if applicant elects a combination of 4 alleles, the response should state the specific alleles in this combination and the claims which read on the elected invention.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-153 are drawn to patentably distinct products, having different structures, physicochemical properties and different functions. The claims encompass nucleic acids having different nucleotide sequences and each containing a different polymorphism. The chemical structure of each allele and of each nucleic acid containing the allele is distinct from each of the other alleles and nucleic acids. For example, a polynucleotide comprising allele 4 of the 222/223 marker of IL-1A is chemically, structurally and functionally distinct from a polynucleotide comprising allele 4 of the gz5/gz6 marker of IL-1A. Each of the nucleic acids binds to a different nucleotide sequence, has a different melting temperature and a different specificity. Additionally, each combination of alleles is distinct from one another, since the particular combinations of alleles (haplotypes) each have a different effect and possess their own functional activity. Accordingly, each of the alleles and combination of alleles is deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their divergent subject matter. Further, these inventions require different database searches that are not co-extensive. For example, a search for the nucleic acid comprising allele 4 of the 222/223 marker of IL-1A would not be co-extensive with a search for the nucleic acid comprising allele 4 of the gz5/gz6 marker of IL-1A. Further, a reference which anticipates or renders obvious the nucleic acid comprising allele 4 of the 222/223 marker of IL-1A would not also necessarily anticipate or render obvious the nucleic acid comprising allele 4 of the

Art Unit: 1634

gz5/gz6 marker of IL-1A. Similarly a finding that nucleic acids comprising allele 4 of the 222/223 marker of IL-1A are novel and unobvious over the prior art would not necessarily extend to a holding that nucleic acids comprising allele 4 of the gz5/gz6 marker of IL-1A are also novel and unobvious over the prior art.

Further, each of the combinations of alleles is distinct from the individual alleles because the combinations of alleles have distinct structural and functional properties, such that the combined haplotypes have distinct effects from one another. Additionally, a reference which renders obvious a single allele will not necessarily also render obvious a combination of these alleles. Similarly, a search indicating that a particular combination of alleles is novel or unobvious would not extend to a holding that a single allele or a different combination of alleles is also unobvious.

Accordingly, examination of these distinct inventions would pose a serious burden on the Office and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

Art Unit: 1634

accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
June 12, 2006


CARLA J. MYERS
PRIMARY EXAMINER